Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevailer@gibbonslaw.com

Christine A. Gaddis
GIBBONS P.C.
141 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801
cgaddis@gibbonslaw.com

Attorneys for Plaintiff
American Regent, Inc.

OF COUNSEL:

Dennies Varughese, Pharm. D.
Uma Everett
Adam LaRock
Christina Dashe
Alex Alfano
Ryan Conkin
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1101 K Street, NW, 10th Floor
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
ueverett@sternekessler.com
alarock@sternekessler.com
cdashe@sternekessler.com
aalfano@sternekessler.com
rconkin@sternekessler.com

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE SELENIOUS ACID LITIGATION	C.A. No. 2:24-cv-07791 (BRM) (CLW) (Consolidated)

PLAINTIFF'S ANSWER TO DEFENDANTS DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES, LTD.'S ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

Plaintiff/Counterclaim Defendant American Regent, Inc. ("ARI"), by its undersigned attorneys, hereby responds to the Answer, Separate Defenses, and Counterclaims of Defendants/Counterclaimants Dr. Reddy's Laboratories, Inc. ("DRL Inc.") and Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") (collectively, "DRL") (ECF No. 63; hereinafter, the "Counterclaims") as follows:

GENERAL DENIAL

ARI denies all allegations in DRL's Counterclaims except for those specifically admitted below. With respect to the allegations made in the Counterclaims, upon knowledge with respect to ARI's own acts, and upon information and belief as to other matters, ARI responds and alleges as follows:

THE PARTIES

1. On information and belief, ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Admitted.

2. DRL Ltd. is a company organized and existing under the laws of India, having a place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, India 500034.

ANSWER: On the basis of DRL's Answer to Paragraph 3 in the Counterclaims, admitted.

3. DRL Inc. is a company organized and existing under the laws of New Jersey, having its principal place of business at 600 College Road East, Princeton, New Jersey, 08540.

ANSWER: On the basis of DRL's Answer to Paragraph 5 in the Counterclaims, admitted.

NATURE OF THE ACTION

4. DRL seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that United States Patent No. 12,150,957 ("the '957 patent") is invalid and/or not infringed.

ANSWER: Paragraph 4 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that DRL purports to bring the Counterclaims under the patent laws of the United States and 28 U.S.C §§ 2201 and 2202. ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI denies that the Counterclaims have merit or that DRL is entitled to any relief on its Counterclaims.

JURISDICTION AND VENUE

5. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 5 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that DRL purports to bring the Counterclaims under the patent laws of the United States and 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI denies that the Counterclaims have merit or that DRL is entitled to any relief on its Counterclaims.

6. Counterclaim This Court has personal jurisdiction over ARI because, among other reasons, it subjected itself to the jurisdiction of this Court by filing its complaint here.

ANSWER: Paragraph 6 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest personal jurisdiction for purposes of this action only. ARI otherwise denies the allegations of Paragraph 6.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), and by ARI's choice of forum.

ANSWER: Paragraph 7 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest venue in this judicial district for the purposes of this action only. ARI otherwise denies the allegations of Paragraph 7.

8. ARI alleged in its complaint that there is an actual and justiciable controversy between the parties as to the noninfringement and invalidity of the '957 patent.

ANSWER: Paragraph 8 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and DRL regarding DRL's infringement of the '957 patent. ARI specifically denies that there is a present, genuine, and justiciable controversy regarding invalidity of the '957 patent.

BACKGROUND

A. FDA Approval of New Brand Name Drugs

9. The Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

ANSWER: Paragraph 9 states legal conclusions for which no response is required. To the extent a response is required, admitted.

10. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

ANSWER: Paragraph 10 states legal conclusions for which no response is required. To the extent a response is required, admitted.

11. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. §§ 355(b)(1)(A)(viii), (b)(2), (c)(2); 21 C.F.R. §§ 314.53(a), (b)(1), (c)(2).

ANSWER: Paragraph 11 states legal conclusions for which no response is required. To the extent a response is required, admitted.

12. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

ANSWER: Paragraph 12 states legal conclusions for which no response is required. To the extent a response is required, admitted.

13. FDA's duties with respect to the Orange Book are purely ministerial. If the NDA holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. §§ 355(b)(1)(A)(viii), (c)(2); 21 C.F.R. § 314.53(e)-(f). FDA does not substantively review the submitted patent information to ensure either that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

ANSWER: ARI lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 13 as pled and denies those allegations on that basis.

B. FDA Approval of New Generic Drugs

14. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

ANSWER: Paragraph 14 states legal conclusions for which no response is required. To the extent a response is required, admitted.

15. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

ANSWER: Paragraph 15 states legal conclusions for which no response is required. To the extent a response is required, admitted.

16. Among other things, an ANDA must contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

ANSWER: Paragraph 16 states legal conclusions for which no response is required. To the extent a response is required, admitted.

17. A "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

ANSWER: Paragraph 17 states legal conclusions for which no response is required. To the extent a response is required, admitted.

18. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of each of its paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

ANSWER: Paragraph 18 states legal conclusions for which no response is required. To the extent a response is required, admitted.

C. DRL's ANDA and ARI's Complaint

19. DRL submitted ANDA No. 218639 ("DRL's ANDA") to obtain FDA approval to engage in the commercial manufacture, use, and sale of Selenious acid Injection, USP 600 mcg/10 mL (60 mcg/mL) and 60 mcg/mL of Selenium ("DRL's Proposed ANDA Products").

ANSWER: ARI admits that DRL notified ARI that DRL submitted ANDA No. 218639 to market generic versions of selenious acid solutions, intravenous, 60 mcg/mL and 600 mcg/10 mL. ARI otherwise denies the allegations in Paragraph 19.

20. On information and belief, ARI is the holder of NDA No. 209379 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL) selenium/2 mL), under Section 505(b) of the FFDCA.

ANSWER: Admitted.

21. Selenious acid products have been on the market since as early as 1990. For example, on information and belief, ARI has marketed an unapproved Selenium Injection product for over thirty years. In particular, the Multi-Discipline Review for NDA No. 209379 represents that ARI has marketed the unapproved product Selenium Injection (65.4 mcg/mL selenious acid equivalent to 40 mcg/mL selenium) available in 10-mL and 30-mL vials since 1990 as an additive to parenteral nutrition. *See* NDA No. 209379, Multi-Discipline Review at 25.

ANSWER: ARI admits that a Multi-Discipline Review was conducted with regard to NDA No. 209379. That document speaks for itself. ARI lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 21 and denies them on that basis.

22. ARI has represented that it has marketed selenious acid under NDA 209379 since July 1, 2019. Specifically, the FDA National Drug Code ("NDC") Directory lists a "Start Marketing Date" of "07/01/2019" for "selenious acid" having a "Product NDC" of 0517-6560. FDA represents that the "[m]arketing start date is the date the labeler reports that the product has entered commercial distribution." *See* https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory.

ANSWER: ARI admits that DRL purports to characterize incomplete portions of the FDA NDC Directory. That document speaks for itself. ARI lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 22 and denies them on that basis.

23. On information and belief, ARI caused the ’957 patent to be listed in the Orange Book, as a patent that purportedly claims the drug listed in, and/or purportedly claims a method of using the drug for which ARI submitted, NDA No. 209379.

ANSWER: Admitted.

24. The ’957 patent, entitled “Trace element compositions, methods of making and use” was issued on November 26, 2024.

ANSWER: Admitted.

25. On information and belief, ARI is the assignee of the ’957 patent.

ANSWER: Admitted.

26. On December 13, 2024, ARI filed the present lawsuit alleging infringement of the ’957 patent.

ANSWER: Admitted.

27. On the basis of ARI’s suit alleging that DRL infringes the ’957 patent, there has been and now is an actual, substantial, continuing and justiciable controversy between ARI and DRL as to whether the claims of the ’957 patent are invalid and/or infringed, and whether any injunctive remedy is available to ARI, which are of sufficient immediacy and reality to warrant the issuance of declaratory judgment.

ANSWER: Paragraph 27 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and DRL regarding DRL’s infringement of the ’957 patent. ARI further admits that there is an actual, substantial, continuing and justiciable controversy between ARI and DRL as to whether injunctive relief is an appropriate remedy for DRL’s infringement of the ’957 patent. ARI specifically denies that there is an actual, substantial, continuing and justiciable controversy between ARI and DRL regarding invalidity of the ’957 patent.

COUNT I: DECLARATORY JUDGMENT OF INVALIDITY OF THE ’957 PATENT

28. DRL incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

29. The claims of the ’957 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

ANSWER: Denied.

30. DRL is entitled to a declaration that all claims of the ’957 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, 112, 115, 116, and/or improper inventorship, or other judicially-created bases for invalidity.

ANSWER: Denied.

COUNT II: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’957 PATENT

31. DRL incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

32. ARI claims to be the owner of all legal rights, title, and interests in the ’957 patent, including the right to enforce the ’957 patent.

ANSWER: Admitted.

33. DRL’s Proposed ANDA Products have not infringed, will not infringe, and are not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’957 patent.

ANSWER: Denied.

34. Unless ARI is enjoined, DRL believes that ARI will continue to assert that DRL’s Proposed ANDA Products infringe the claims of the ’957 patent and will continue to interfere with DRL’s business with respect to DRL’s Proposed ANDA Products.

ANSWER: ARI lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 34 as pled and denies those allegations on that basis. To the extent an answer is required, ARI admits that ARI alleged DRL infringes the claims of the '957 patent. ARI otherwise denies the allegations in Paragraph 34.

35. DRL will be irreparably harmed if ARI is not enjoined from continuing to assert the '957 patent and from interfering with DRL's business.

ANSWER: Denied.

36. DRL is entitled to a declaratory judgment that DRL's Proposed ANDA Products have not infringed, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '957 patent.

ANSWER: Denied.

COUNT III: DECLARATORY JUDGMENT OF NO INJUNCTIVE REMEDY FOR THE '957 PATENT

37. DRL incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

38. Neither the patent holder nor any exclusive licensee will in fact experience any harm from any DRL sales of DRL's Proposed ANDA Products that have nexus to the claims of the '957 patent.

ANSWER: Denied.

39. ARI cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages even if infringement of a valid and enforceable patent were presumed.

ANSWER: Denied.

40. ARI is not entitled to any injunctive remedy of any kind.

ANSWER: Denied.

PRAYER FOR RELIEF

ARI denies that DRL is entitled to any judgment or relief against ARI and, therefore specifically denies Paragraphs (A)–(H) of Counterclaimant DRL's Prayer for Relief.

Each averment and/or allegation contained in DRL's Counterclaims that is not specifically admitted herein is hereby denied.

ARI requests that judgment be entered in its favor, dismissing DRL's Counterclaims with prejudice, awarding ARI's attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting even further relief as the Court may deem just and proper.

Dated: January 28, 2025

By: s/ Charles H. Chevalier

Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevailer@gibbonslaw.com

Christine A. Gaddis
GIBBONS P.C.
141 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801
cgaddis@gibbonslaw.com

OF COUNSEL:

Dennies Varughese, Pharm. D.
Uma Everett
Adam LaRock
Christina Dashe
Alex Alfano
Ryan Conkin
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1101 K Street, NW, 10th Floor
Washington, DC 20005

(202) 371-2600
dvarughese@sternekessler.com
ueverett@sternekessler.com
alarock@sternekessler.com
cdashe@sternekessler.com
aalfano@sternekessler.com
rconkin@sternekessler.com

Attorneys for Plaintiff
American Regent, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2025, a true and correct copy of Plaintiff's Answer to Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.'s Answer, Separate Defenses and Counterclaims to Plaintiff's Complaint was served by ECF on all counsel of record and electronic mail on all counsel of record for DRL.

Date: January 28, 2025

s/ Charles H. Chevalier

Charles H. Chevalier